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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,555	03/29/2004	Carl-Sebastian Wagner	3401-139	1394

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COHEN, PONTANI, LIEBERMAN & PAVANE  
551 FIFTH AVENUE  
SUITE 1210  
NEW YORK, NY 10176

EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/811,555

Applicant(s)

WAGNER ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to applicant's amendment received on 13 October 2006.

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Specification***

2. Corrections made to the specification are accepted.

#### ***Claim Objections***

3. Corrections made to the claims are accepted.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 12-16, 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris (Patent No. 5,713,867) in view of Dubrul et al. (Patent No. 5,431,676). Morris discloses a dilation pin (Figure 16, element 66) having a tapered distal end (68) and a tubular guide sleeve (61) having a holding element (62, 64) that is separable over the entire length and thickness along at least one line (score line or weakened wall; column 6, lines 15-29) and is capable of maintaining a tissue passage in an empty state (column 5, lines 21-26). The device disclosed by Morris is intended to introduce therapeutic and diagnostic devices, by dilating and supporting the central lumen of a vessel. Therefore, the device is capable of dilating an existing tissue passage in a body.

Morris does not disclose the inside diameter of the tubular guide sleeve (61) corresponds to the diameter of the distal end of the dilation pin. Dubrul et al. disclose a dilating apparatus (Figures 1, 4, and 9). Dubrul et al. teach a tubular guide sleeve (30) having an inside diameter corresponding to the diameter of the dilation pin (80) at the distal end (78). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the sleeve of Morris with a diameter that corresponds to the diameter of the distal end of the dilation pin as taught by Dubrul et al. in order to be able to separate the guide sleeve upon insertion of the dilation pin, which facilitates removal of the sleeve (column 11, lines 23-25 and 33-34) since this configuration removes the unnecessary step of having to tear or peel the sleeve away.

Morris in view of Dubrul et al. disclose a veress canula (Figure 1, element 40) having an outer diameter that corresponds to the inner diameter of the guide sleeve

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(30), since the veress canula passes through the guide sleeve (column 7, lines 27-29, 33-36, 41-42, and 52-55). Figure 16 shows the guide sleeve (30) comprising two diametrically opposite longitudinally extending frangible areas, since it splits completely through both the top and bottom portions of the guide sleeve (30). Morris in view of Dubrul et al. discloses that each frangible area comprises one of a perforation or a regionally reduced wall thickness (Dubrul et al., column 7, lines 17-19). Figure 2 shows the guide sleeve (30) has a distal end (42) that is tapered, since it becomes progressively smaller towards one end. Morris in view of Dubrul et al. further disclose the guide sleeve (30) is manufactured of transparent plastic (polyethylene, fluorinated ethylene propylene, etc.; column 7, lines 11-14).

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Dubrul et al., as applied above, and further in view of Hall et al. (Patent No. 6,939,327 B2).

Morris in view of Dubrul et al. disclose a dilation system as described above, however, does not disclose that the guide sleeve is formed by at least two concentric sleeves. Hall et al. disclose a guide sleeve (Figure 3b, element 82). Hall et al. teach a guide sleeve (82) formed by at least two concentric sleeves (84 and 92); each sleeve (84 and 92) having at least one longitudinally extending frangible area (100 and 102) circumferential displaced from the frangible areas in each other concentric sleeve (column 8, lines 34-38). This dual sheath configuration improves kink resistance (column 8, lines 40-43). Therefore, to construct the guide sleeve of Morris in view of Dubrul et al. with at least two concentric sleeves as taught by Hall et al. would have

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been obvious to one of ordinary skill in the art at the time the invention was made in order to reduce susceptibility to kinking during use.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morris in view of Dubrul et al., as applied above, and further in view of Osypka (Patent No. 4,687,469).

Morris in view of Dubrul et al. disclose a dilation system as described above, however, does not disclose that the dilation pin comprises at least one cutter. Osypka teaches using a severing device (Figure 11, element 7) comprising a cutter (9) in order to sever a guide sleeve (Figure 12, element 6) that is not formed with a slit or with one or more longitudinally extending weakened portions (column 6, line 64 through column 7, line 6). It is obvious that this device could be used as a severing dilation pin.

Therefore, to construct the dilation pin of Morris in view of Dubrul et al. with at least one cutter as taught by Osypka would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate separating a guide sleeve that is not formed with a slit or with one or more longitudinally extending weakened portions.

#### ***Response to Arguments***

9. Applicant's arguments with respect to claims 12-22 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Tyson *MT*  
November 13, 2006

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

*11/20/06*